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09/578,587	04/19/2000	Vilmos Keri	0100-004	5173

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
1651	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,587

Applicant(s)

Keri et al.

Examiner

Irene Marx

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Sep 11, 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 4, 6, and 11-16 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 4, 6, and 11-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

The application should be reviewed for errors. Error, occurs, for example, in the spelling of "Aspegillus" in claim 12. The amendment filed 9/11/02 is acknowledged. Claims 4, 6 and 11-16 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 6 are incomplete in depending on cancelled claims 10 and 5, respectively.

Claim 12 is confusing in lacking proper internal antecedent basis for "the end product".

Is it the strain, mevinolin, the culture medium, etc.

Claim 13 is confusing in lacking clear antecedent basis for "the separating of the mevinolin". Claim 11 is directed to dissolving and recovering mevinolin, but not separating. The step intended is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(a) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 11 is/remain rejected under 35 U.S.C. § 102(e) as being anticipated by Jekkel et al. (US patent 5,403,728). See, e.g. col. 7 et seq. wherein the treatment of biomass of *A. obscurus* MV-1 to obtain mevinolin is first with 2N NaOH, which would be expected to yield at a pH of about 7.5 to 10, and then with sulfuric acid at a pH of about 1.5, which is within the range of 4.5 and 1.

Claims 4, 6 and 11-16 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over Jekkel et al. U.S. Patent No. 5,403,728 taken with Nakamura et al.

Jekkel et al. teaches the treatment of biomass of *A. obscurus* MV-1 to obtain mevinolin first with 2N NaOH, which would be expected to yield at a pH of about 7.5 to 10, and then with sulfuric acid at a pH of about 1.5. The reference differs from the claimed invention in that the reference does not teach the precise pH values and additives recited.

However, Nakamura et al. teach the recovery of derivative of mevinolin from the respective biomass by adjusting the pH first to 10 and then to 3, which is within the range of the claimed process (See, e.g., page 1597). The reference also teaches the addition of ethyl acetate in the recovery process page 1597, last line. The reference differs from the claimed invention in that the product recovered is not mevinolin, but rather 3 α -Hydroxy-3,5-dihydromonacolin L, a product closely structurally related to mevinolin.

Although the references do not teach the precise pH values and additives recited, the adjustment of process parameters such as pH and the addition of a variety of solvents to a process

of recovery of antibiotics for optimization purposes is deemed to be well within the ordinary skill of the art.

Consequently, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Jekkel *et al.* by modifying the pH and additives, as suggested by the teachings of Nakamura *et al.* for a process for the recovery of mevinolin in addition or instead of 3 α -Hydroxy-3,5-dihydromonacolin L with a reasonable expectation of success, for the expected benefit of improving the yield and purity of mevinolin as a cholesterol-lowering drug.

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant refers to an affidavit and/or declaration filed in the parent application. Affidavits and/or declarations, such as those under 37 CFR 1.131 and 37 CFR 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit and/or declaration, the applicant should make the remarks of record in the later application and include a copy of the original affidavit and/or declaration filed in the parent application.

Therefore the rejection is deemed proper and it is adhered to.

Claims 4, 6 and 11-16 are/remain rejected under 35 U.S.C. § 103(a) as being unpatentable over Nakamura *et al.* taken with Tsujita *et al.* and Endo *et al.* for the reasons as stated in the last Office action and the further reasons below.

Nakamura *et al.* teach the recovery of a derivative of mevinolin from the cultured biomass by adjusting the pH first to 10 and then to 3, which is within the range of the claimed process (See, e.g., page 1597). The reference also teaches the addition of ethyl acetate in the recovery process (See, e.g., page 1597, last line). The reference differs from the claimed invention in that the product recovered is not mevinolin, but rather 3 α -Hydroxy-3,5-dihydromonacolin L, a product closely structurally related to mevinolin. However, Tsujita *et al.*

teaches the recovery of mevinolin from biomass filtrate using a pH of about 10, while Endo *et al.* teach a pH of about 3 for the same process.

Although the references do not teach the precise pH values and additives recited, the adjustment of process parameters such as pH and the addition of a variety of solvents to a process of recovery of antibiotics for optimization purposes is deemed to be well within the ordinary skill of the art.

Consequently, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Nakamura *et al.* by using the process for the recovery of mevinolin in addition or instead of 3 α -Hydroxy-3,5-dihydromonacolin L with a reasonable expectation of success, in view of the teachings of Tsujita *et al.* and Endo *et al.* for the expected benefit of improving the yield and purity of mevinolin as a cholesterol-lowering drug.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant did not address this rejection.

Therefore the rejection is deemed proper and it is adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592, (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651